and Research of the Food and Drug Administration.

(b) *Classification.* Class I (general controls).

[45 FR 60638, Sept. 12, 1980, as amended at 53 FR 11253, Apr. 6, 1988]

### § 864.9100 Empty container for the collection and processing of blood and blood components.

(a) *Identification.* An empty container for the collection and processing of blood and blood components is a device intended for medical purposes that is an empty plastic bag or plastic or glass bottle used to collect, store, or transfer blood and blood components for further processing.

(b) *Classification.* Class II (performance standards).

[45 FR 60638, Sept. 12, 1980]

### § 864.9125 Vacuum-assisted blood collection system.

(a) *Identification.* A vacuum-assisted blood collection system is a device intended for medical purposes that uses a vacuum to draw blood for subsequent reinfusion.

(b) *Classification.* Class I (general controls). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60639, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

### § 864.9145 Processing system for frozen blood.

(a) *Identification.* A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

(b) *Classification.* Class II (performance standards).

[45 FR 60639, Sept. 12, 1980]

### § 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use.

(a) *Identification.* Blood group substances of nonhuman origin for in vitro diagnostic use are materials, such as blood group specific substances prepared from nonhuman sources (e.g., pigs, cows, and horses) used to detect, identify, or neutralize antibodies to various human blood group antigens. This generic type of device does not include materials that are licensed by the Center for Biologics Evaluation and Research of the Food and Drug Administration.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60640, Sept. 12, 1980, as amended at 53 FR 11253, Apr. 6, 1988; 63 FR 59225, Nov. 3, 1998]

### § 864.9175 Automated blood grouping and antibody test system.

(a) *Identification.* An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.

(b) *Classification.* Class II (performance standards).

[45 FR 60641, Sept. 12, 1980]

### § 864.9185 Blood grouping view box.

(a) *Identification.* A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60641, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

### § 864.9195 Blood mixing devices and blood weighing devices.

(a) *Identification.* A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.

(b) *Classification.* Class I (general controls). The manual device is exempt